

premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Biological Product Review, CBER.

(b) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director, Office of Device Evaluation, CDRH.

[56 FR 58759, Nov. 21, 1991, as amended at 62 FR 2555, Jan. 17, 1997; 62 FR 67271, Dec. 24, 1997]

§ 5.34 Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.

(a) Each center director is authorized to select members of, and consultants to, scientific and technical FDA advisory committees under that center's management to serve temporarily as voting members on another advisory committee under that center's management when expertise is required that is not available among current voting standing members of a committee or to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. When additional voting members are added to a committee to provide needed expertise not available among current voting standing members of a committee, a quorum will be based on the total of regular and added members. Authority to select temporary voting members to advisory committees if such voting members are serving on an advisory committee managed by another center has not been redelegated. This authority will continue to be exercised by the Commissioner or his designee.

(b) Each center director is authorized, under 18 U.S.C. 208(b)(1), to sign conflict of interest waivers for special government employees without substantial interest to serve as consultants to advisory committees or in any other capacity within the centers except as advisory committee members.

[58 FR 39142, July 22, 1993]

§ 5.35 Enforcement activities.

(a) Designated officers and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FDA-200A, Identification Record, and Form FDA-200B, Specification of General Authority, are authorized:

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law; to make seizures of items under section 702(e)(5) of the Federal Food, Drug, and Cosmetic Act (the act); and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act, the Federal Caustic Poison Act, the Import Milk Act, the Filled Milk Act, the Tea Importation Act, and sections 351 and 354 through 361 of the Public Health Service Act.

(2) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(b) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to conduct examinations, investigations, or inspections under the act relating to counterfeit drugs and issued the Food and Drug Administration Official Credential consisting of Form FDA-200D, Special Authority for Criminal Investigators, is authorized to do the following:

(1) As set forth under section 702(e)(1) through (e)(5) of the act:

(i) Carry firearms;

(ii) Serve and execute search warrants and arrest warrants;

(iii) Execute seizure by process issued pursuant to libel under section 304 of the act;

(iv) Make arrests without warrant for an offense under the act with respect to counterfeit drugs if the offense is committed in the presence of the criminal investigator or, in the case of a felony, if the investigator has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(v) Make, prior to the institution of libel proceedings under section 304(a)(2) of the act, seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or the criminal investigator has reasonable grounds to believe that they are, subject to seizure and condemnation under section 304(a)(2) of the act.

(2) Perform such other functions under the act, or any other law, as the Commissioner of Food and Drugs may prescribe.

(3) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(c) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to provide specialized law enforcement support involving criminal investigations under the Federal Food, Drug, and Cosmetic Act (the act), and other duties as assigned by the Commissioner, and issued the Food and Drug Administration Official Credential consisting of Form FDA-200E, Special Authority for Criminal Investigative Specialists, is authorized to receive information as to all matters relating to such act and regulations promulgated under the act.

(d) The Food and Drug Administration's official credentials referred to in paragraphs (a), (b), and (c) of this section are described as follows:

(1) Form FDA-200A entitled "Identification Record" bears a color photograph, a description, and the signature of the holder, an identification number, an expiration date, the Department of Health and Human Services' seal with blue imprint, on the left of the photograph, and the Food and Drug Administration's symbol, on the right of the photograph.

(2) Form FDA-200B entitled "Specification of General Authority" bears the holder's name, his or her general authority, an identification number, an expiration date, the Commissioner's signature, the names of the Department of Health and Human Services, the Public Health Service, and the

Food and Drug Administration. The form is superimposed with the Department's seal with blue imprint.

(3) Form FDA-200D, entitled "Special Authority for Criminal Investigators," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under 21 U.S.C. 334 and 372 and other duties as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigator's badge with blue imprint.

(4) Form FDA-200E, entitled "Special Authority for Criminal Investigative Specialists," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under the act, and other duties under the law, as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigative specialist's badge with blue imprint.

[49 FR 19973, May 11, 1984, as amended at 53 FR 22293, June 15, 1988; 56 FR 23788, May 24, 1991; 58 FR 494, Jan. 6, 1993; 58 FR 42496, Aug. 10, 1993; 59 FR 47799, Sept. 19, 1994]

§ 5.36 Certification following inspections.

Regional Food and Drug Directors and District Directors are authorized to issue certificates of sanitation under § 1240.20 of this chapter.

[60 FR 15871, Mar. 28, 1995]

§ 5.37 Issuance of reports of minor violations.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 309 of the Federal Food, Drug,